

MISSOURI BOARD OF PHARMACY



ANNUAL REPORT



FY 2018

Michael L. Parson, Governor
State of Missouri

Chlora Lindley-Myers, Director
Department of Insurance, Financial Institutions
and Professional Registration

Kathleen (Katie) Steele Danner, Director
Division of Professional Registration



Michael L. Parson
Governor
State of Missouri

Kathleen (Katie) Steele Danner, Division Director
DIVISION OF PROFESSIONAL REGISTRATION

Department of Insurance,
Financial Institutions and
Professional Registration
Chlora Lindley-Myers, Director

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Kimberly A. Grinston
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To The Honorable Governor Michael L. Parson:

In compliance with § 338.140.3, RSMo, the Missouri Board of Pharmacy is pleased to submit its Annual Report which contains the proceedings of the Board for the fiscal year ending June 30, 2018 ("FY 18"). The Board's mission is to protect the public in the regulation of pharmacy practice. The Board of Pharmacy is pleased to report another successful year.

Respectfully yours,
MISSOURI BOARD OF PHARMACY
By:

A handwritten signature in black ink, appearing to read "K A Grinston".

Kimberly Grinston
Executive Director



Department of Insurance, Financial Institutions and
Professional Registration
Division of Professional Registration
Missouri Board of Pharmacy

FY 2018

Board Members

Christian Tadrus, PharmD., President
Douglas Lang, R.Ph., Vice-President
Barbara A. Bilek, PharmD., Member
Christina Lindsay, PharmD., Member
Pamela Marshall, R.Ph, Member
Anita K. Parran, Public Member
Vacant Positions (1)

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Kimberly A. Grinston, J.D., Executive Director

TABLE OF CONTENTS



Executive Summary	5
About the Board	7
Board Operations	8
Financial Summary	10
Licensing	12
Complaint Handling	20
Disciplinary Actions	23
Inspections/Investigations	27
Compounded Drug Testing	29
Rulemaking	30
Strategic Initiatives	31

Executive Summary



This Annual Report covers the activities of the Missouri Board of Pharmacy from July 1, 2017 to June 30, 2018 (FY18). The Board is pleased to announce another successful regulatory year as reflected below:

Board Operations

- The Board held a total of 21 meetings during FY 18, including, five (5) regular session meetings, eleven (11) conference call meetings and five (5) email ballot meetings. The Board also hosted an additional nineteen (19) Working Group and Advisory Committee meetings.
- The Board received/responded to approximately 8,035 telephone calls in FY 18, representing a 79% increase which is likely attributable to higher call volume and enhanced call tracking mechanisms/procedures introduced in FY 18.
- As part of its ongoing efforts to protect patients through voluntary compliance, the Board hosted eight (8) educational seminars, including, three (3) live programs and five (5) webinars. Educational programs were free and approved for pharmacist continuing education.

Financial Overview

- The Board's total appropriation and authorized transfers for FY18 was \$2,685,466. Of the amount appropriated, the Board expended \$ 2,277,777.88.
- The Board experienced an overall 9.5% increase in revenue. Board expenditures increased by 6.1%.
- To ensure compliance with § 338.070, pharmacy technician renewal fees were decreased from \$ 35 to \$ 10 and pharmacy and drug distributor renewal fees decreased from \$ 450 to \$ 150. The Board will continue to monitor revenue trends to ensure compliance with § 338.070.

Licensing Summary

- Total licensees/registrants increased from 36,910 licensees/registrants in FY17 to 37,916 licensees/registrants in FY18, representing a 2.7% increase.
- The number of licensed pharmacists increased by 5% to 11,325 licensees, reversing a slight decline in FY 17.
- Total registered pharmacy technicians remained consistent with a 1.3% increase to 19,912 technicians.
- Total licensed pharmacies and drug distributors/drug distributor registrants remained consistent, however, new pharmacy permit applicants increased by 10%. 57% of licensed pharmacies are located in the state of Missouri while 43% are non-resident licensees.

Complaint Handling

- The Board issued final dispositions on approximately 842 complaints/cases in FY18 which included 299 Department of Revenue tax suspension complaints and 543 non-tax related complaints, representing a 2% decrease from FY 17.
- The Board received/opened 848 new complaints in FY 18, representing a minor 1% decrease from FY 17.
- Of the 848 complaints received/opened, 544 complaints were practice-related complaints (64%) while 304 complaints were non-practice related Missouri Department of Revenue tax compliance cases (approx. 36%).

Executive Summary



Disciplinary Actions

- The Board issued disciplinary action in 427 cases in FY18. One-hundred and twenty-eight (128) practice related disciplinary actions were issued (30%) while the remaining 299 cases involved non-practice related Department of Revenue tax suspensions (70%).
- Overall, practice-related disciplinary actions decreased by 13.5%, including, a 12.5% decrease in pharmacist discipline and a 25.8% decrease in pharmacy technician discipline.

Inspections

- Board inspectors conducted a total of 1,260 inspections of pharmacies and drug distributors. Despite staffing changes, 257 investigations were completed in FY 18 representing a 4% increase.
- Violations were observed or a Compliance Notice was issued in approximately 70% of inspections conducted, a decrease of 5%. Significantly, the number of inspections resolved with no violations noted increased by 22%.

Compounded Drug Testing

- In 2003, the Board initiated a program to test drug preparations compounded by pharmacies. 76.4% of products tested in FY18 were satisfactory while 23.6% were unsatisfactory.

Rulemaking

- The Board promulgated the following rules in FY18:
 - 20 CSR 2220-2.025 (Non-Resident Pharmacies)
 - 20 CSR 2220-2.085 (Electronic Prescriptions and Medication Orders)
 - 20 CSR 2220-2.650 (Standards of Operation for a Class J: Shared Services Pharmacy)
 - 20 CSR 2220-4.010 (General Fees)
 - 20 CSR 2220-6.040 (Administration by Medical Prescription Order)

Board Initiatives

- The Board completed the 2020 Rule Review initiative launched in FY 17. The goal of the 2020 Rule Review initiative was to review and update the Board's rules to clarify regulatory requirements and eliminate duplicate or unnecessary regulation.
- In addition to the 2020 rule review, the Board conducted four (4) public hearings in FY 18 to receive public input on the Board's rules pursuant to Executive Order 17-03.
- As part of its ongoing educational campaign, the Board hosted the 2017 Pharmacy Patient Safety Conference and the 2018 Patient Safety and Compliance Conference. The Board also held a Pharmacy Regulatory Update Conference in Springfield, Missouri (similar programs were hosted in St. Louis and Kansas City during FY 17).

About the Board



Mission Statement

The Board's mission is to serve and protect the public by providing an accessible, responsible and accountable regulatory system that:

- Protects the public from incompetence, misconduct, gross negligence, fraud, misrepresentation or dishonesty;
- Licenses only qualified and competent professionals, and;
- Ensures compliance with professional standards and federal and state pharmacy law.

ABOUT THE MISSOURI BOARD OF PHARMACY

The Missouri Board of Pharmacy was statutorily created in 1909 and has served the citizens of Missouri through the regulation of pharmacy practice for over 100 years. The Board of Pharmacy is an autonomous Board within the Division of Professional Registration, an agency of the Department of Insurance, Financial Institutions and Professional Registration.

MEMBERSHIP

The Board consists of seven (7) members, including, six (6) licensed pharmacists actively engaged in the practice of pharmacy and one (1) public member. By statute, at least one member must provide pharmaceutical services to a hospital, skilled nursing facility or intermediate care facility on a full-time basis. Board members are appointed by the Governor and confirmed by the Missouri Senate. All members hold office for five (5) years from the date of their appointment or until their successors have been appointed and qualified. The Board annually elects a president and vice-president, each of whom serve one (1) year terms.

FUNCTIONS

Pursuant to Chapter 338, RSMo, the Board has superintending control over the practice of pharmacy in the State of Missouri and its primary duties consist of:

- Ensuring compliance with Chapter 338, RSMo, and the rules of the Board;
- Licensing/registering pharmacists, pharmacy technicians, intern pharmacists, pharmacies and drug distributors;
- Investigating complaints within the Board's statutory jurisdiction;
- Disciplining licensees which may include, public censure, probation, suspension or revocation of a licensee/registrant;
- Inspection of pharmacies and drug distributors; and
- Approval of preceptors and intern training facilities.

Board Operations



The Board held a total of 21 meetings during FY 18, including, five (5) regular session meetings, eleven (11) conference call meetings and five (5) email ballot meetings. In addition to Board meetings, the following Board Advisory Committee/Working Group meetings were held during FY18:

- Drug Distributor Advisory Committee (1 meeting)
- Hospital Advisory Committee (8 meetings)
- Long-Term Care Working Group (2 meetings)
- Nuclear Pharmacy Working Group (4 meetings)
- Sterile Compounding Sub-Committee (4 meetings)

Staff

The following staff were employed by the Board during FY18:

Staff

- **Kimberly Grinston, J.D., Executive Director**
- Jennifer Luebbert, Administrative Coordinator
- Laura Henke, Pharmacy/Drug Distributor Coordinator
- Christa Nilges, Senior Office Support Assistant
- Shelda Sternberg, Compliance Coordinator *
- Sarah Decker, Compliance Coordinator
- Kimberly Hatfield, Pharmacy Technician Coordinator
- Regina Walker, Pharmacist Coordinator

* Retired or resigned in FY 18.

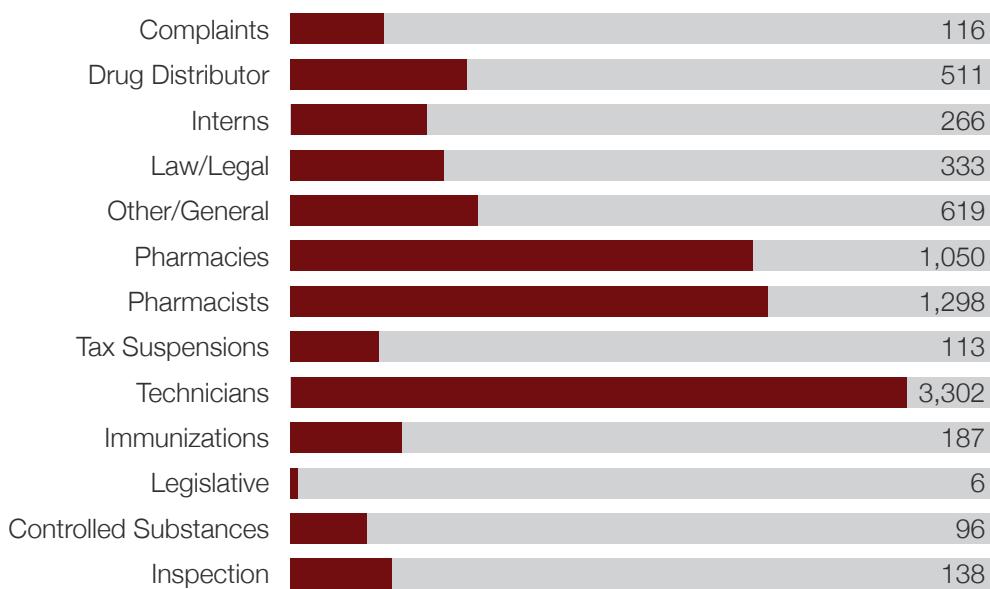
Inspectors

- **Tom Glenski, R.Ph., Chief Inspector**
- Bennie Dean, R.Ph.
- Katie DeBold, PharmD.
- Joe Dino, R.Ph. *
- Andrea "Andi" Miller, PharmD.
- Scott Spencer, R.Ph.
- Lisa Thompson, R.Ph.
- Daniel Vandersand, R.Ph.
- Elaina Wolzak, R.Ph.
- Barbara Wood, R.Ph.

Office Activities

The Board received/responded to 8,035 telephone calls during FY18, representing a 79% increase which is likely attributable to higher call volume and enhanced call tracking mechanisms/procedures introduced in FY 18. Major call topic areas are identified below:

(FY18 Calls by Category)



* Pharmacist category includes licensing, continuing education and audit related questions.

Board Operations



Education/Training

As part of its ongoing efforts to promote voluntary compliance, the Board hosted the following compliance webinars in FY18 (participants were awarded free continuing education credit) :

- 2017: Legislative Update
- 2017: Pharmacist Naloxone Dispensing
- 2017: Sterile Compounding One Year Later
- 2018: Pharmacy Technician Compliance Update
- 2018: Missouri Bureau of Narcotics and Dangerous Drugs Regulatory Update

The Board also hosted the following live programs:

- 2018 Patient Safety & Compliance Conference (June 21, 2018)
- 2017 Pharmacy Patient Safety Conference (St. Louis- October 24, 2017)
- 2017 Board Regulatory Update (Springfield- December 13, 2017)

Gold Certificates

The following individuals received Gold Certificates during FY 18 representing fifty (50) years of active service as a Missouri licensed pharmacist:

- Stanley E. Beiermann
- Roger S. Bellas
- Melvin R. Bird
- Clayton Claybaker
- Gary F. Crabtree
- Arnon R. Crawford
- Morris P. Deewall
- Russell M. Donnell
- Frank D. Farrell
- Jimmy L. Garrison
- Bernard J. Goodman
- Inge L. Grunbaum
- Steven E. Hartwig
- Henry T. Hayden
- Ronald V. Keeler
- Samuel W. Kernohan
- Patrick E. Magee
- William E. Maleski
- Clayton F. McCruden
- Diana L. McDaniel
- Evan P. Mcnemar
- Barry J. Naeger
- Frank W. Newkirk
- John T. Price
- William A. Rall
- William J. Rogers
- Peggy J. Shuman
- Lillie L. Smith
- Gerald A. Sobel
- Dale L. Stafford
- David R. Stevenson
- Robert A. Suschnick
- Benny E. Thomas
- James E. Tilghman
- Dennis G. Tilly
- Frederick E. Tonnes
- Charles E. Varni
- Allen B. Weiner
- Robert S. Zucco

Financial Summary



Financial Overview

The Missouri Board of Pharmacy's appropriation for fiscal year ending June 30, 2018, was as follows:

Personal Service	\$ 1,089,799
Expense and Equipment	\$ 668,418
Criminal History Fund	\$ 5,000
Transfers*	\$ 922,249
	<hr/>
	\$ 2,685,466

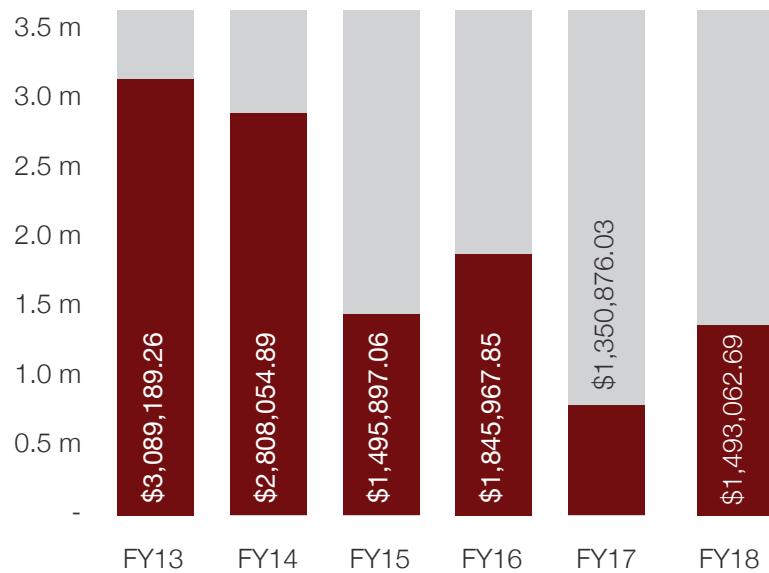
Of the amount appropriated, the Board expended \$ 2,277,777.88 in FY 18 as follows:

Personal Service	\$ 1,056,671.19 (46.39%)
Expense and Equipment	\$ 438,943.64 (19.27%)
Transfers*	\$ 782,163.05 (34.34%)

**Transfers include costs/transfers for rent, the Division of Professional Registration, IT transfers, licensee refunds, attorney general services, Administrative Hearing Commission, DIFP Allocated Expenses and OA Allocated Expenses.*

Revenue Received:

The Board of Pharmacy is statutorily obligated to establish fees as necessary to administer the provisions of Chapter 338, RSMo. Section 338.070, RSMo, provides fees must be appropriate so that revenue produced does not substantially exceed the cost and expense of administering Chapter 338. In compliance with § 338.070, the Board lowered renewal fees in FY 18 for pharmacy technicians from \$ 35 to \$ 10 and for pharmacies/drug distributors from \$ 450 to \$ 150. Despite the reduction, the Board experienced an overall 9.5% increase in FY18 revenue as reflected below:



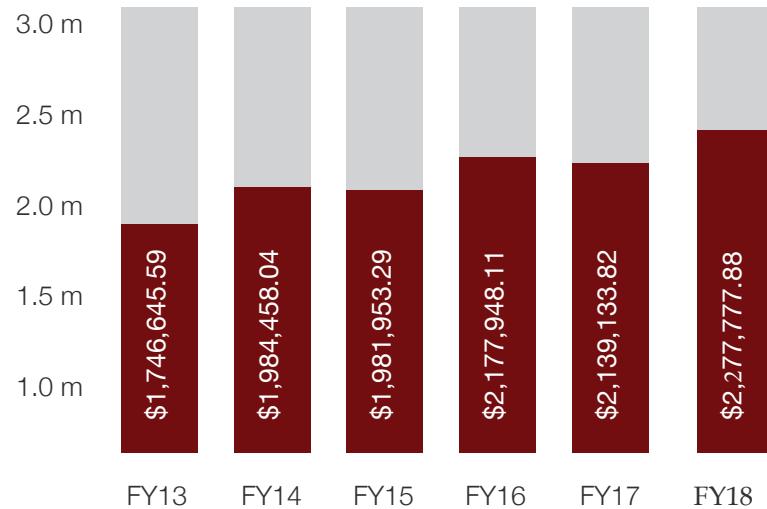
The Board will continue to monitor revenue trends to ensure compliance with § 338.070, RSMo.

Financial Summary



Board Expenditures:

Board expenditures remained relatively consistent from FY 18 with a slight 6.1% increase as reflected below:





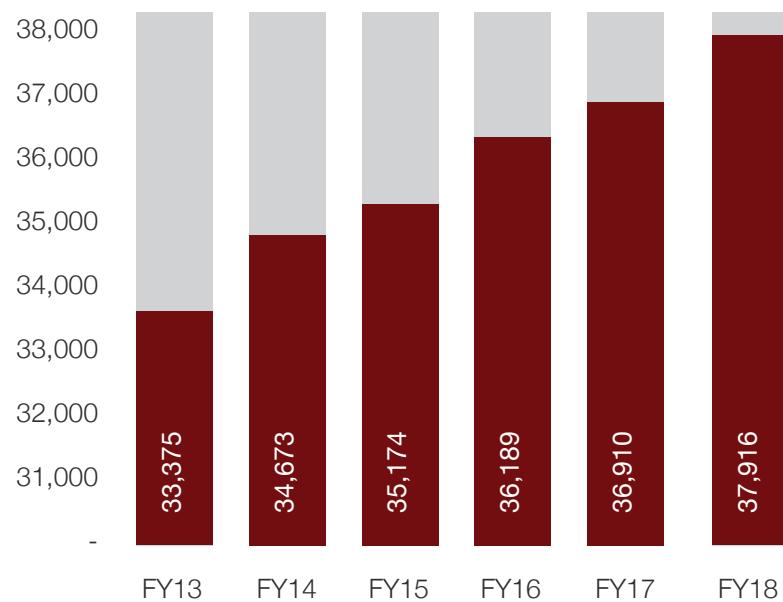
Licensing Summary

Pursuant to Chapter 338, the Board licenses and regulates pharmacists, intern pharmacists, pharmacy technicians, pharmacies and drug distributors.

- The Board's total licensee/registrant count increased 2.7% from 36,910 licensees/registrants in FY17 to 37,916 licensees/registrants in FY18.
- 6,677 new licenses/registrations were issued for all license classes (excludes temporary permits)
- Licensing totals at the close of FY18 are provided by classification below:

LICENSING TOTALS	
Drug Distributors (licensed & temporary)	1,412
Drug Distributor Manufacturer Registrants	95
Intern Pharmacists	2,210
Pharmacists (active and inactive)	11,325
Pharmacists (temporary)	8
Pharmacies (instate, non-resident and temporary)	2,695
Pharmacy Technicians	20,171
TOTAL	37,916

Total Licensees/Registrants by Fiscal Year

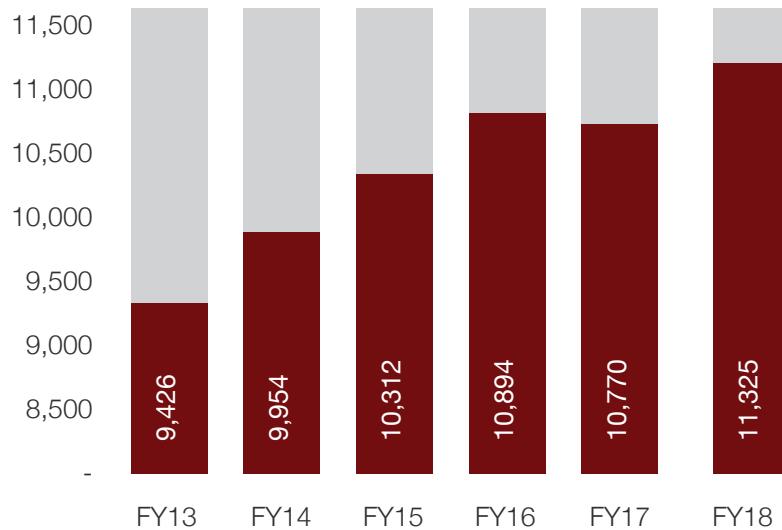


Licensing



Pharmacists:

Total licensed pharmacists increased by 5% to 11,325 licensees reversing a minor 1.1% decline in FY 17



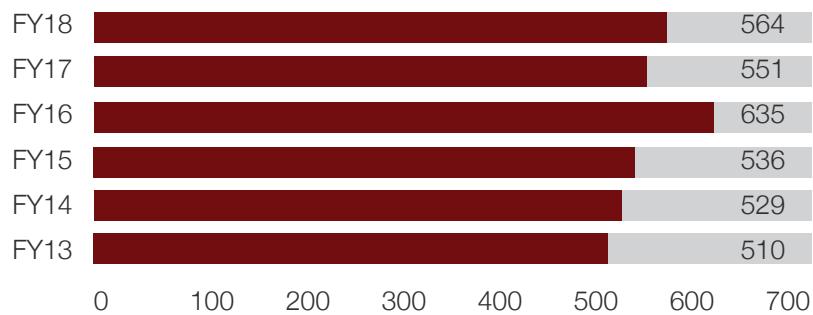
The total number of active vs. inactive Missouri pharmacists both resident and non-resident are reflected below:

Active Licensees	10,984
Male	4,878
Female	6,106
Inactive Licensees	341
TOTAL LICENSED PHARMACISTS	11,325

***Inactive pharmacists are not authorized to practice in Missouri but remain licensed.*

Number of New Pharmacist Licenses Issued

A 2% increase in newly licensed pharmacists occurred in FY18 as reflected below:



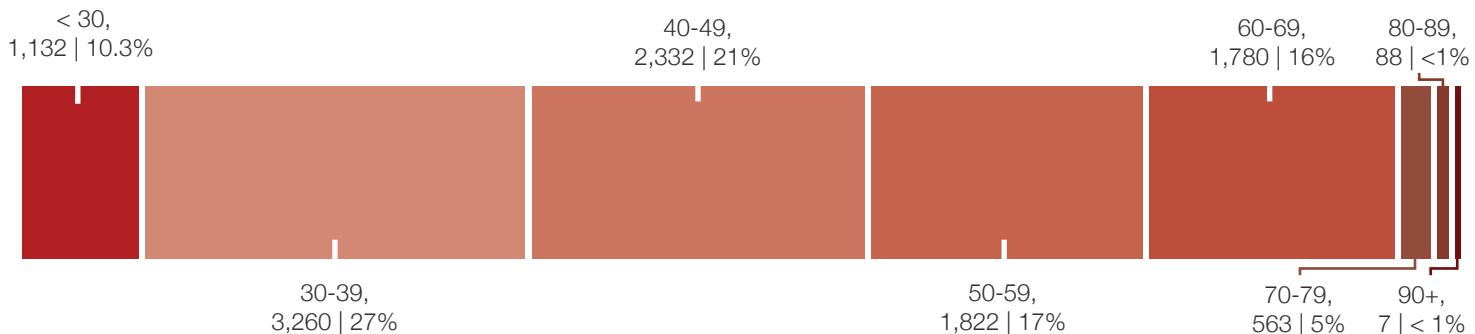
Licensing



Active Pharmacists By Age Group (Resident and Non-Resident) [#, %]

No significant changes occurred in the number of active pharmacists categorized by age. Forty percent (40%) of licensed Missouri pharmacists are age 39 and under with the remaining sixty percent (60%) at age 40 or above.

(Pharmacist Distribution by Age)



Pharmacists Residing in Missouri

No significant changes occurred in actively licensed resident vs. non-resident pharmacists. Approximately 62% of pharmacists licensed by the Board reported a Missouri address as reflected below:

Resident Pharmacists	6,763
Non-Resident Pharmacists	4,221
Total Missouri Resident Pharmacists	10,984

Administration & Immunizations:

Pursuant to § 338.010, RSMo, pharmacists are authorized to administer medication by prescription order and to administer vaccines pursuant to a protocol with a Missouri licensed physician, upon filing a Notification of Intent with the Board. At the end of FY 18:

- 2,729 pharmacists were authorized to administer medication by prescription.
- 2,962 pharmacists were authorized to administer immunizations by protocol.

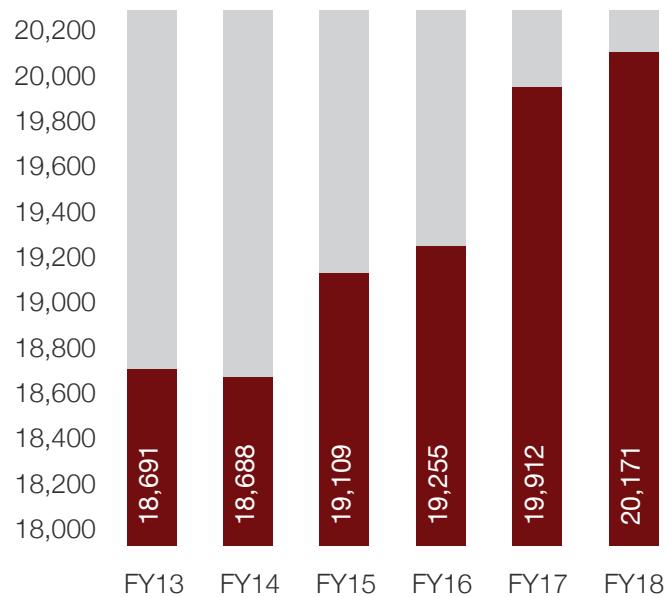
Medication Therapy Services:

Section 338.010, RSMo, authorizes the Board to issue a Certificate of Medication Therapeutic Plan Authority (MTS certificate) which allows pharmacists to provide medication therapy services. A total of 2,940 pharmacists held a MTS certificate at the end of FY18 representing an 11% increase from FY17.



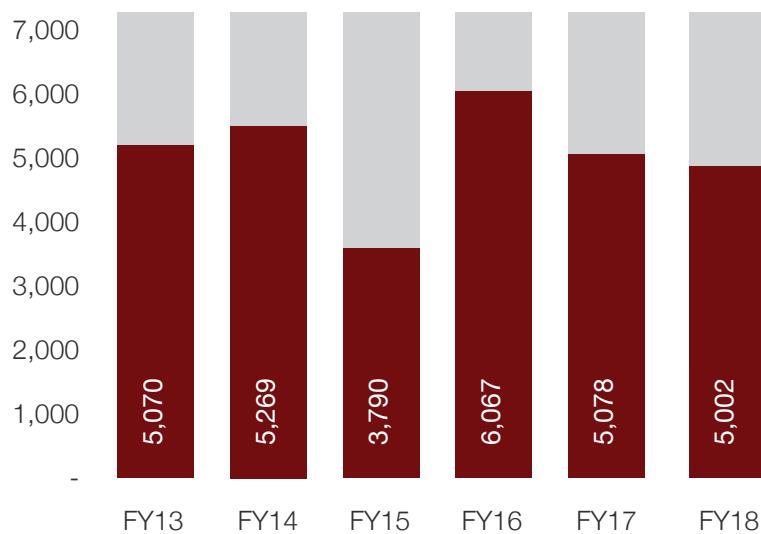
Pharmacy Technicians:

The number of registered pharmacy technicians remained consistent as reflected below:



New Pharmacy Technician Registrations Issued

The percentage of newly registered pharmacy technicians also remained consistent with a minor 1.5% decrease:



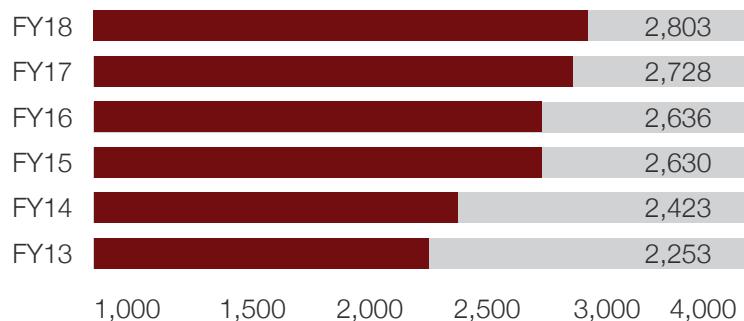


Pharmacy Summary:

PHARMACY PERMIT TOTALS	
Instate Pharmacies	1,533
Non-Resident Pharmacies	1,162
Temporary Pharmacies	8
TOTAL	2,703

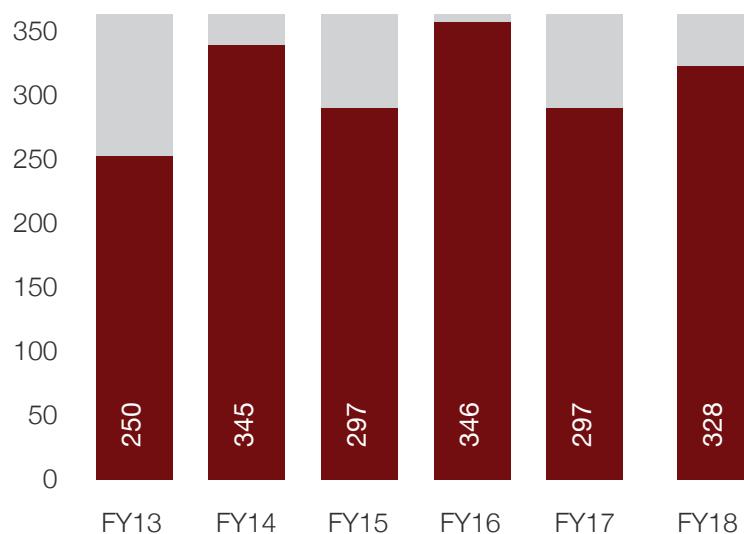
Pharmacy Permitholders By Fiscal Year

Total licensed pharmacies decreased to 2,703 pharmacies as reflected below:



New Pharmacy Permits Issued

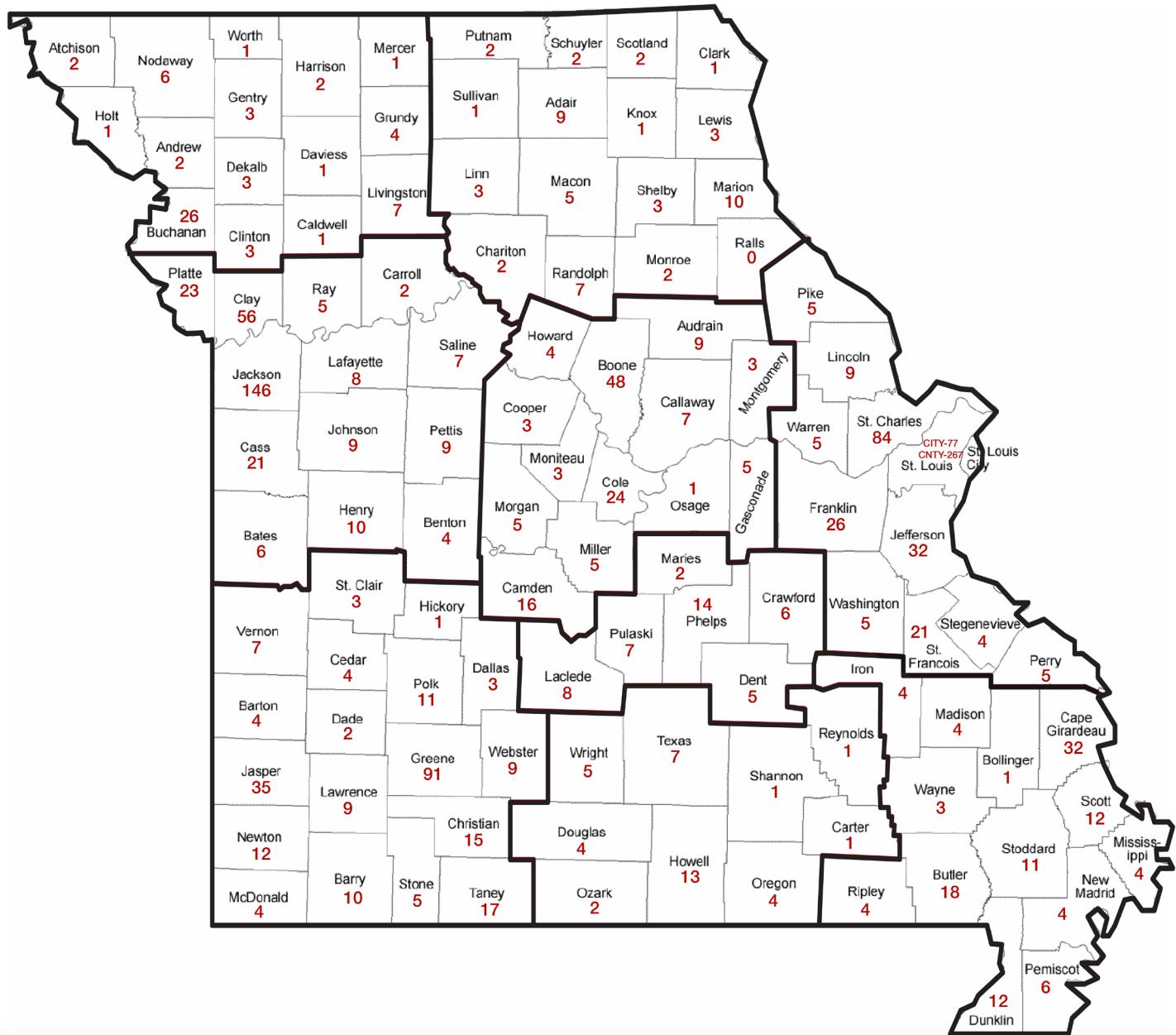
A 10% increase in new pharmacy permits occurred in FY 18 which is consistent with the Board's licensing history in renewal fiscal years:



Licensing



Missouri Pharmacies by County



Statistics to Note:

- Number of counties with 0 pharmacies: 1 (Ralls County)
- Number of counties with < 10 pharmacies: 87
- Number of counties with 100+ pharmacies: 2 (St. Louis & Jackson County)

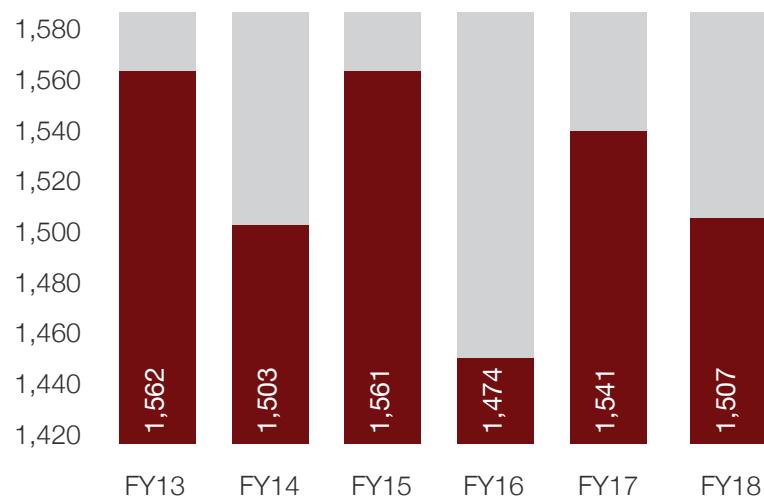


Drug Distributor Summary:

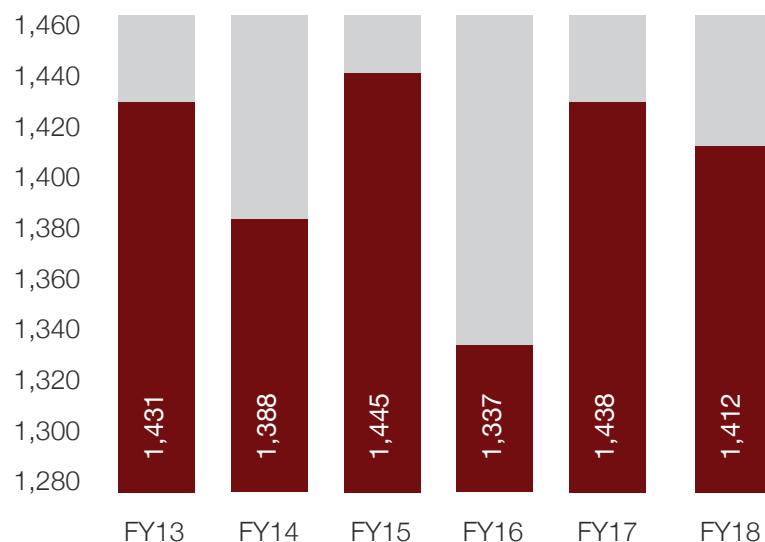
All in-state drug companies that ship/transfer legend pharmaceuticals or drug-related devices are required to be licensed as a Missouri drug distributor. Additionally, out-of-state drug companies or manufacturers that ship/transfer legend drugs or drug-related devices into Missouri must hold a Missouri drug distributor license.

TOTAL DRUG DISTRIBUTORS & DRUG DISTRIBUTOR REGISTRANTS BY FISCAL YEAR

The total number of licensed drug distributors and drug distributor registrants decreased by 2% to 1,507 licensees/registrants (1,412 drug distributors and 95 drug distributor registrants). The Board historically experiences a decrease in drug distributors/registrants during a drug distributor renewal year as with FY18.



TOTAL DRUG DISTRIBUTORS BY FY

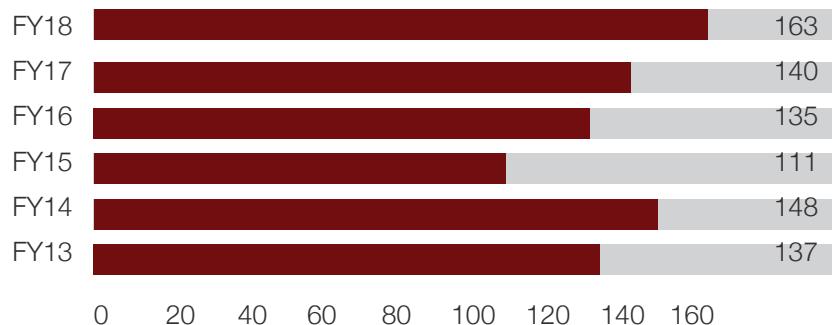


Licensing

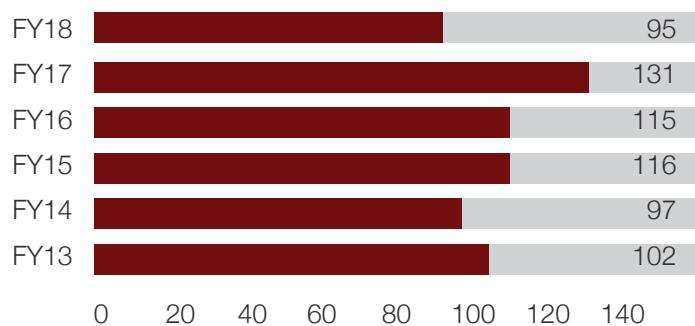


NEW DRUG DISTRIBUTORS LICENSED

A 16% increase occurred in newly licensed drug distributors as reflected below:

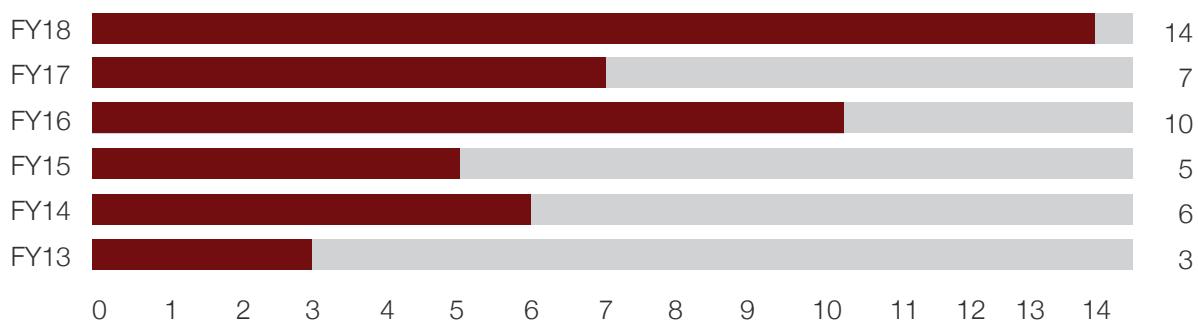


TOTAL DRUG DISTRIBUTOR REGISTRANTS BY FY



NEW DRUG DISTRIBUTOR REGISTRANTS

The number of drug distributor registrants increased by 100% while still historically lower:



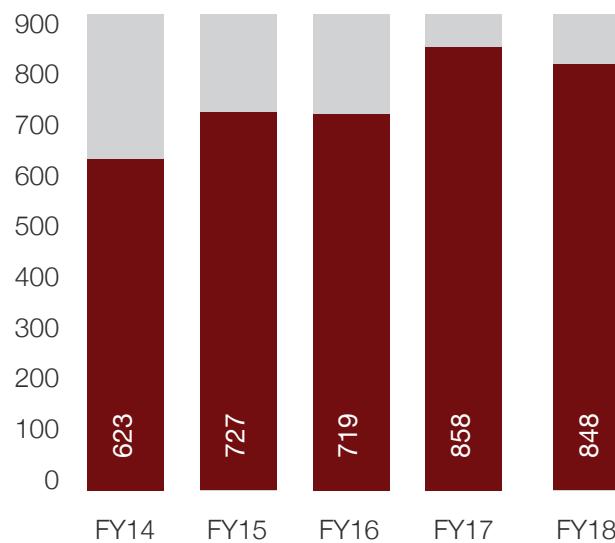
Complaint Summary



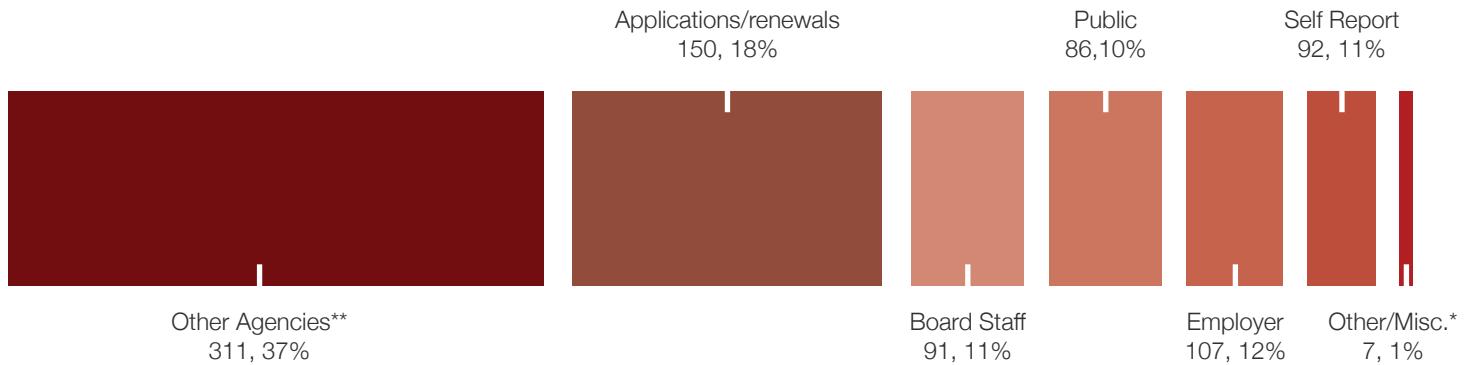
Complaint Summary

All matters investigated or officially reviewed by the Board are recorded as complaints and processed according to Board procedures. The Board received/opened 848 new complaints in FY 18 representing a minor 1% decrease from FY17. Of the 848 complaints received/opened, 544 complaints were practice-related complaints (64%) while 304 complaints were non-practice related Missouri Department of Revenue tax compliance cases (approx. 36%).

Complaints Handled by FY



Complaints by Source



** Includes Dept. of Revenue tax suspensions (304 cases)

Complaint Summary



FY18 COMPLAINTS BY CATEGORY (Non-Tax Related)

Abandonment	2
Advertising	1
Alcohol Use/Suspected Alcohol Impairment	6
Audit Findings	2
Compounding	5
Criminal History	3
Disciplinary Action in Another State	82
Dispensing Error	4
Diversion/Theft of Drugs	30
Drugs	30
Exam Failure	1
Fraud (Other)	2
Fraud (Billing)	2
Fraudulent Prescription	2
Drug Impairment (Suspected/Actual)	2
Improper Controls	80
Immunization/Administration	31
Improper Dispensing	18
Inspection Violation	8
Licensure Applicant	143
Loss of Drugs	8
Malpractice	2
Misbranding	2
Misconduct	2
No Jurisdiction/Other	6
Other/Misc.	10
Unlawful Sale of Drugs/Sale of Drugs for Illegal Purposes	2
Substitution	2
Theft of Money	21
Unauthorized Dispensing	2
Unlicensed Practice	24
Unprofessional Conduct	3
Unsanitary Facility	1
Unsanitary Pharmacy	2
Unsupervised Dispensing	1
Violation of Disciplinary Order	2

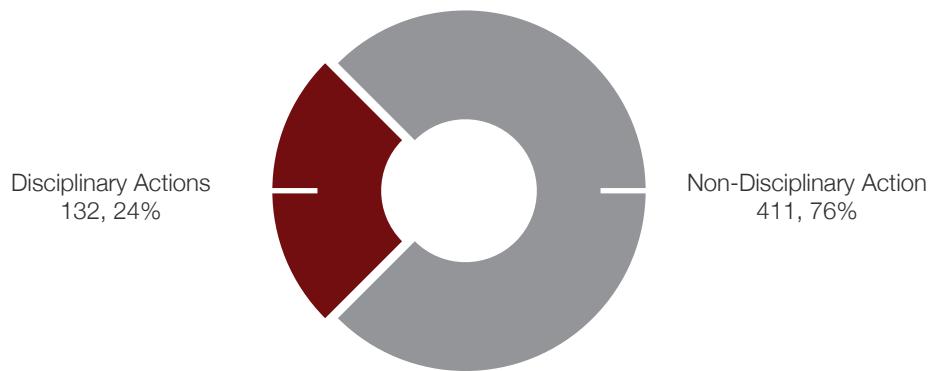
Complaint Summary



COMPLAINT DISPOSITIONS

The Board issued final dispositions on approximately 842 complaints/cases in FY18 which included 299 Department of Revenue tax suspension complaints and 543 non-tax related complaints, representing a 2% decrease from FY 17.2. The 543 non-tax related cases were disposed of as follows:

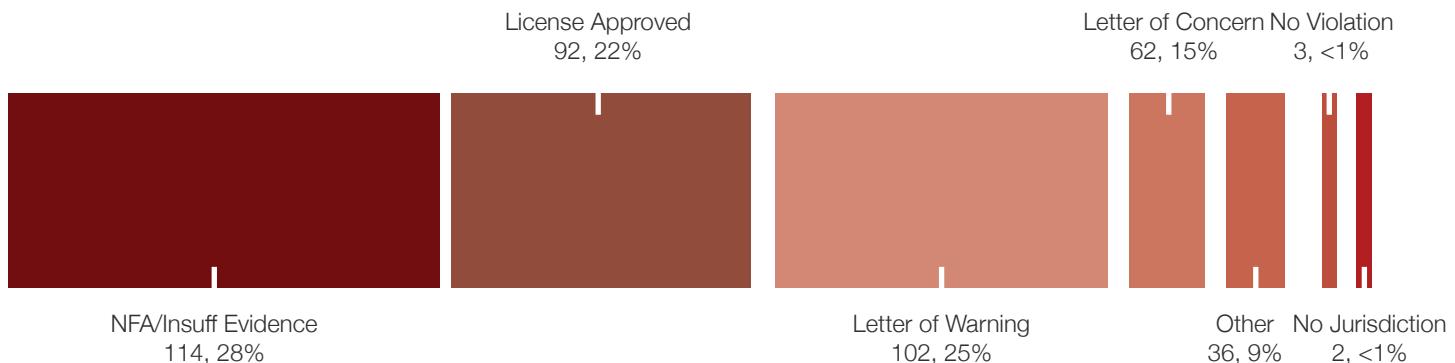
(Non-Tax Related Complaint Dispositions)



The 842 complaint dispositions includes complaints received in prior fiscal years but finally determined in FY18. As a result, the number of complaints disposed of in FY18 will not equal the number of new complaints received.

SUMMARY OF NON-DISCIPLINARY COMPLAINT RESOLUTIONS:

The following action was taken in the 411 non-tax related complaints closed without disciplinary action in FY18: (see Disciplinary Action section for complaints closed with disciplinary action)



* Other: Application Withdrawn (2), Closed (18), Closed but Flagged for Future Review (10), Misc. (2), Refer to other Bd/Agency (2), Voluntarily Complied (1), Voluntary Surrender in lieu of Discipline (1)

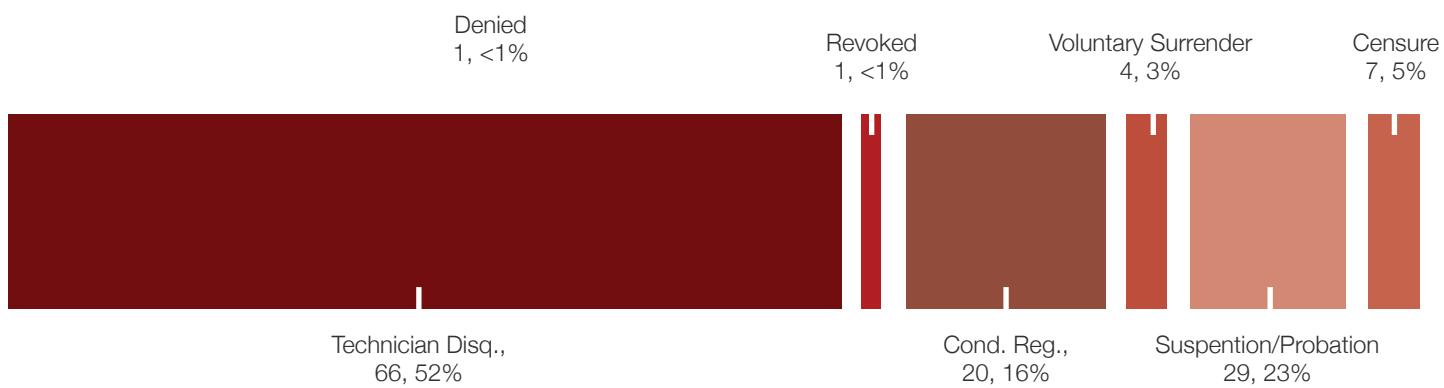
Disciplinary Actions



Summary of Disciplinary Action

The Board issued disciplinary action in 427 cases in FY18. One-hundred and twenty-eight (128) practice related disciplinary actions were issued (30%) while the remaining 299 cases involved non-practice related Department of Revenue tax suspensions (70%). Practice-related disciplinary actions decreased by 13.5%, including, a 12.5% decrease in pharmacist discipline and a 25.8% decrease in pharmacy technician discipline.

The following disciplinary action was taken in the 128 practice-related disciplinary actions issued in FY 18:



DISCIPLINARY ACTIONS BY CATEGORY

Drug Distributors Probated	4
Technician Registrations Suspended under § 324.010 (tax purposes)	285
Technicians Disqualified	66
Technicians Placed on Conditional Employment	20
Intern Licenses Denied	1
Intern Licenses Suspended under § 324.010 (tax purposes)	3
Intern Licenses Voluntarily Surrendered (Treated As Discipline)	1
Pharmacist Licenses Censured	3
Pharmacist Licenses Probated	15
Pharmacist Licenses Revoked	1
Pharmacist Licenses Suspended followed by Probation	1
Pharmacist Licenses Suspended under § 324.010 (tax purposes)	11
Pharmacist Licenses Voluntarily Surrendered (Treated As 1 Discipline)	1
Pharmacy Permits Censured	4
Pharmacy Permits Probated	9
Pharmacy Permits Voluntarily Surrendered (Treated As Discipline)	2
TOTAL	427

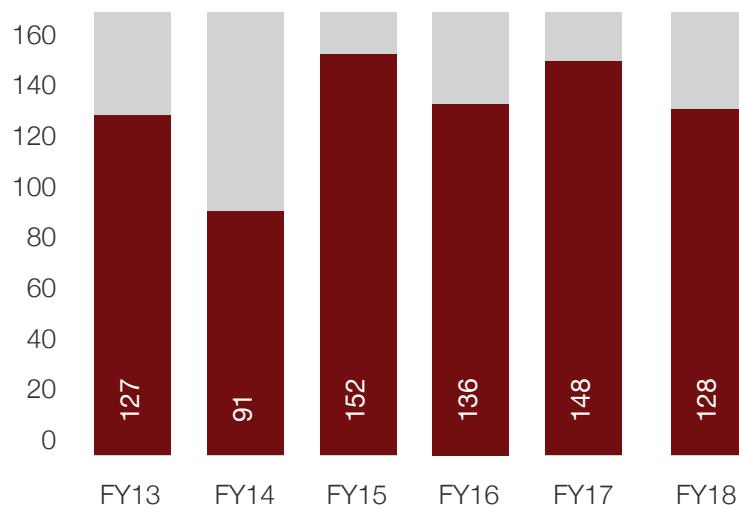
Disciplinary Actions



PRACTICE RELATED DISCIPLINARY ACTIONS *

Total practice related disciplinary actions decreased by 13.5% from FY17. Eighty-six (86) pharmacy technicians, 21 pharmacists, 2 intern pharmacists, 15 pharmacies and 4 drug distributors were disciplined for practice-related issues during FY18.

(Total Practice-Related Disciplinary Actions by FY)



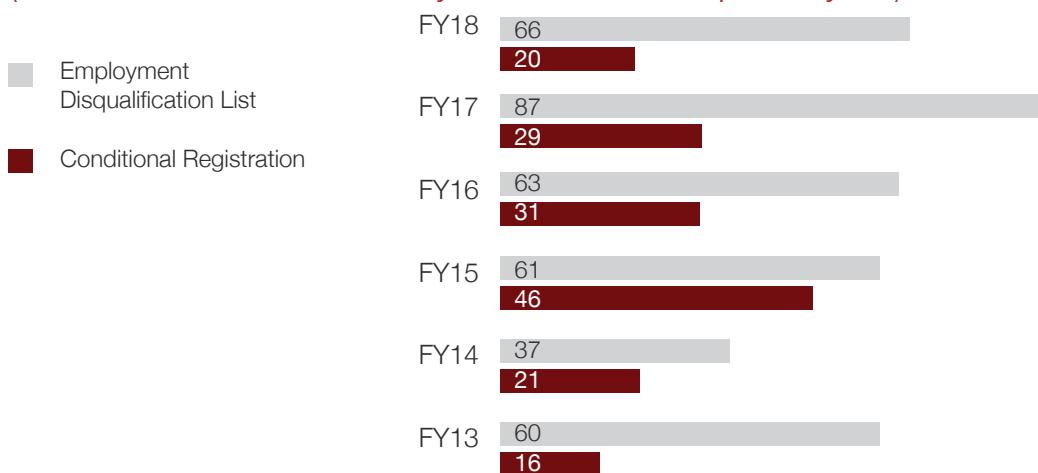
* Does not include tax suspensions pursuant to § 324.010, RSMo.

PHARMACY TECHNICIAN DISCIPLINE

Eighty-six (86) pharmacy technicians were disciplined for practice-related reasons, comprising 67% of all practice-related disciplinary actions issued by the Board in FY18.

Overall practice-related technician discipline decreased by 25.8%, including, a 24% decrease in technicians placed on the Employment Disqualification List and a 31% decrease in technicians issued a conditional registration. Significantly, total practice-related technician discipline decreased for the first time since FY 14.

(Practice Related Pharmacy Technician Discipline by FY)



Disciplinary Actions



GROUNDS FOR TECHNICIAN EMPLOYMENT DISQUALIFICATION (Cause for EDL / # Disciplined)

- Alcohol Use/Prior Impairment (4)
- Criminal History (13)
- Diversion (18)
- Misconduct/Unauthorized Dispensing (2)
- Prior Disciplinary Action/Violation of Discipline (2)
- Illegal Drug Usage/Positive Drug Test (16)
- Theft (Non-Drug Related) (10)
- Unlawful Sell of Drugs (1)

GROUNDS FOR TECHNICIAN CONDITIONAL REGISTRATION (Cause for CR/ # Disciplined)

- Alcohol Use/Suspected Impairment (1)
- Criminal History (13)
- Improper/Prior admitted drug use (2)
- Improper/Unauthorized Dispensing (2)
- Theft (Non-Drug Related) (1)
- Unlicensed activity (Working while suspended/expired) (2)

PHARMACIST DISCIPLINE BY FY:

Pharmacist practice-related discipline decreased by 12.5% representing the first decrease since FY 14:

	FY14	FY15	FY16	FY17	FY18
Censure	7	5	6	6	3
Probation	6	5	14	13	15
Suspension	0	2	0	0	
Suspension/Probation	2	4	4	0	1
Revocation	2	1	3	1	1
Voluntary Surrender (treated as discipline)	--	--	--	4	1
TOTAL	17	17	27	24	21

Disciplinary Actions



PHARMACY DISCIPLINE BY FY

Pharmacies experienced an increase in discipline which may be attributable to increased education on Missouri's requirement to report out-of-state discipline which became effective in FY 2017. The following disciplinary action was taken against pharmacies in FY 18:

	FY14	FY15	FY16	FY17	FY18
Censure	2	9	4	0	4
Probation	9	12	8	7	9
Revocation	0	0	2	0	0
Voluntary Surrender	0	0	0	0	2
TOTAL	11	21	14	7	15

DRUG DISTRIBUTOR DISCIPLINE BY FY

Similar to pharmacies, drug distributors experienced an increase in discipline although the overall number of disciplinary actions remained historically low:

	FY14	FY15	FY16	FY17	FY18
Censure	0	0	0	0	0
Probation	0	3	1	0	4
Voluntary Surrender	0	0	0	0	0
TOTAL	0	3	1	0	4

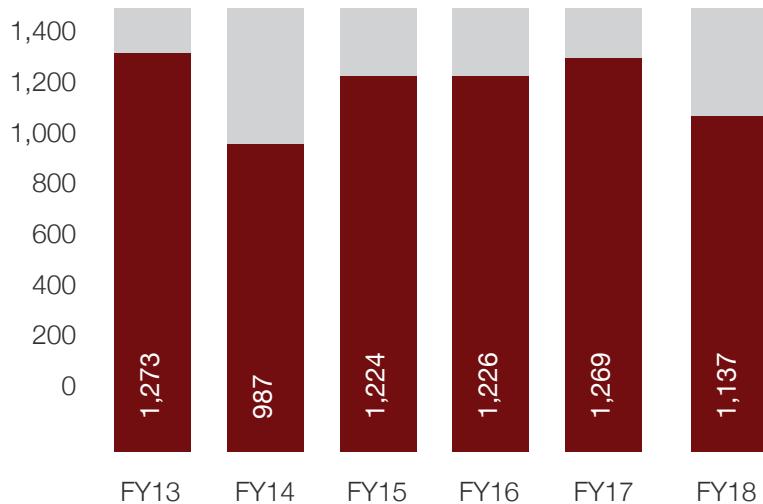
Inspections\Investigations



Inspection/Investigation Summary

The Board conducts new and routine inspections of all Missouri located pharmacies and drug distributors. Board inspectors also conduct investigations as assigned.

- 1,137 regulatory inspections were conducted in FY 18 representing a 10% decrease that is attributable to retirement of a Board inspector and training of new staff during the fiscal year.
- 968 pharmacy inspections and 169 drug distributor inspections were conducted. Thirty- five (35) drug distributors were exempt from inspection pursuant to 20 CSR 2220-5.040 as authorized for facilities inspected by the U.S. Food and Drug Administration.
- The Board continues to inspect all sterile compounding pharmacies annually.
- A total of 257 investigations were completed in FY18 by Board staffinspectors,representing a 4% increase in investigations completed despite staffing changes due to retirement.



INSPECTION FINDINGS

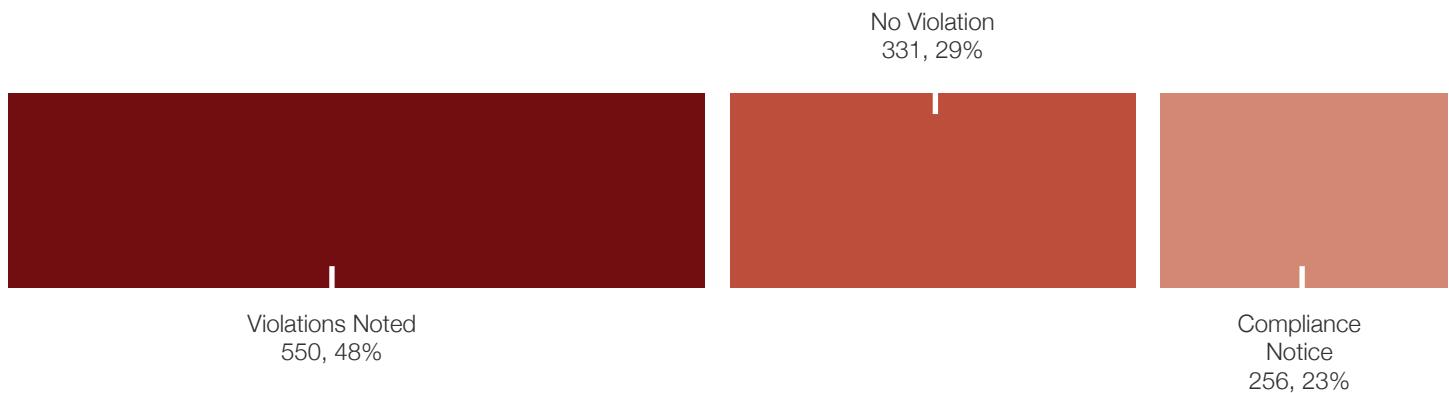
At the conclusion of an inspection, the inspector may initiate one of the following resolutions:

- **Observation Report:** Issued if no compliance issues are identified at the time of inspection or if compliance violations are noted that can generally be corrected and do not require further review/documentation.
- **Compliance Notice:** Issued if compliance concerns are discovered that require official documentation of corrective measures or in instances of multiple or repeat compliance violations.
- **Quality Assurance Report:** Issued if there is a specific question regarding the dispensing/handling of a particular prescription and/or drug.
- **Investigation:** An investigation may be initiated during an inspection if additional factual information may be necessary to assess compliance.



FY17 INSPECTION RESULTS*

Approximately 70.5% of Board inspections resulted in violations noted or a compliance notice being issued as reflected below:



Compliance notices issued after inspection increased by 8%, violations noted increased by 7% while no violation findings remained consistent with a 1% decrease.

** Includes inspection results for follow-up inspections and investigations.*

Compounded Drug Testing



Testing Summary

In 2003, the Board initiated a program to test drug preparations compounded by pharmacies. All preparations are tested for potency and, if applicable, sterility and endotoxins. The tables listed below are for the fiscal year ending June 30, 2018:

Dosage Form	Tests Performed
Capsule	18
Cream/Ointment	18
Injectable solution	10
I.V. solution	9
Oral suspension	3
Sublingual tablet	2
Suppository	2
Nebulizer solution	1
Troche	6
Vaginal capsule	1
Vaginal cream	1
Vaginal suppository	1

Test Results	Tests Performed	Percentage
Satisfactory	55	76.4%
Unsatisfactory	17	23.6%
Total	72	100%

All unsatisfactory results were related to potency failures. An acceptable potency range is considered +/- 10% of the expected potency, unless a U.S.P. monograph states a different range for a specific preparation. Failing potency results ranged from 64.4% to 175.3%. Pharmacies are notified of unsatisfactory results and asked to complete a quality assurance review of their compounding practices and provide a corrective action plan.

Drugs With Unsatisfactory Results	
Alprostadil/Papaverine/Phentolamine Injection	Pyridoxine Injection
Budesonide Capsule	Sildenafil Suppository
Cyclobenzprine/Gabapentin/Ibuprofen/Prilocaine Cream	Sildenafil Troche
Econazole/Triamcinolone Acetonide Cream	Sildenafil Troche
Estradiol/Testosterone Cream	Methimazole topical cream
Fluorouracil/Salicylic Acid Cream	Naltrexone capsule
Gabapentin/Ibuprofen/Nifedipine/Pentoxyfilline/Prilocaine Cream	Ondansetron I.V. solution
Ketamine/Gabapentin/Diclofenac/Lidocaine Cream	Papaverine/Phentolamine Mesylate/Prostaglandin injection
Naltrexone Capsule	Progesterone troche
Ondansetron I.V. Solution	Quinacrine HCl capsule
Progesterone Troche	Spironolactone oral suspension
Ketamine/Gabapentin/Diclofenac/Lidocaine Cream	Tetracaine lollipop

Rulemaking



Rule Changes

The Board continued to review Missouri's pharmacy rules to ensure appropriate and consistent regulation. The following rules were promulgated by the Board in FY18:

Promulgated Rules

PROMULGATED RULES		
20 CSR 2220-2.025	Non-Resident Pharmacies	Clarified and updated Missouri's non- resident licensing requirements
20 CSR 2220-2.085	Electronic Prescriptions and Medication Orders	Removed unnecessary requirements and modernized rule language to accommodate current electronic systems
20 CSR 2220-2.650	Standards of Operation for a Class J: Shared Services Pharmacy	Clarified and streamlined Missouri's Class-J pharmacy requirements, created licensure exemptions for pharmacies dispensing medication to another pharmacy for administration by a licensed healthcare professional
20 CSR 2220-4.010	General Fees	Reduced pharmacy technician, pharmacy and drug distributor renewal fees
20 CSR 2220-6.040	Administration by Medical Prescription Order	Significantly updated and streamlined requirements for administration by medical prescription order

Strategic Initiatives



Strategic Initiatives

As part of its regulatory mission, the Board continued its efforts to protect Missouri citizens and enhance Board operations. The Board approved/sponsored the following in FY 18:

LEGISLATIVE PROPOSALS

The following legislative proposals were approved by the Board for the 2017-2018 legislative session:**

- Implementation of the Drug Quality and Security Act: Would establish licensing requirements for third-party logistic providers and drug outsourcers as defined by the federal Drug Quality and Security Act.
- Continuing Education: Would amend § 338.060, RSMo, to clarify that pharmacists are required to obtain thirty (30) hours of continuing education every biennial renewal period.
- Pharmacy Technicians: Would establish training and education requirements for Missouri pharmacy technicians. A grandfathering clause would be incorporated for currently licensed technicians.

** Legislative proposals are subject to Governor approval.

Compliance:

The Board continued its campaign to encourage and promote compliance and patient safety. In addition to the Board's webinars, the Board sponsored/hosted the following free continuing education programs in FY18:

- 2017 Pharmacy Patient Safety Conference- St. Louis (10-24-17)- Information was provided on ways to enhance and promote patient safety in pharmacy practice. Topics included effective patient communication, opioid safety and preventing dispensing errors. Speakers included representatives from Health Literacy Missouri, the St. Louis College of Pharmacy, the Missouri Bureau of Narcotics and Dangerous Drugs and Board inspectors.
- Pharmacy Regulatory Update- Springfield (12-13-17): The seminar provided information on recent regulatory/legislative changes along with inspector compliance observations and tip. (similar programs were hosted in St. Louis and Kansas City during FY 17).
- 2018 Patient Safety & Compliance Conference- St. Louis (6-21-18): To maximize outreach, the Board voted to host combined patient safety and compliance conferences throughout the state in 2018. The initial program was held in St. Louis and included presentations from the Center for Patient Safety, the Missouri Bureau of Narcotics and Dangerous Drugs and Board inspectors. (Kansas City, Springfield and Columbia programs were scheduled for FY 19).

RULE REVIEW

The Board initiated a 2020 Rule Review initiative in FY 16 to review all Board regulations prior to 2020. The goal of the initiative was:

1. Eliminating duplicate or unnecessary regulation;
2. Ensuring rule appropriateness and consistency; and
3. Updating and modernizing rule language.

Executive Order 17-03 was subsequently issued requiring all state agencies to review their rules to decrease burdensome/unnecessary regulatory impact.

Strategic Planning Initiatives



RULE REVIEW CONTINUED

The Board completed its 2020 Rule Review initiative in FY 18 with review of the following rules:**

- 20 CSR 2220-2.110 (PRN Refills)
- 20 CSR 2220-2.120 (Transfer of Prescription Information for the Purpose of Refill)
- 20 CSR 2220-2.130 (Drug Repackaging)
- 20 CSR 2220-2.800 (Vacuum Tube Drug Delivery System)
- 20 CSR 2220-2.950 (Automated Filling Systems)
- 20 CSR 2220-2.190 (Patient Counseling)
- 20 CSR 2220-2.400 (Compounding Standards of Practice)
- 20 CSR 2220-2.500 (Nuclear Pharmacy- Minimum Standards for Operation)
- 20 CSR 2220-2.600 (Standards of Operation for a Class F: Renal Dialysis Pharmacy)
- 20 CSR 2220-2.675 (Standards of Operation/Licensure for Class-L Veterinary Pharmacies)
- 20 CSR 2220-5.010 (Drug Distributor Advisory Committee)
- 20 CSR 2220-5.020 (Drug Distributor Licensing Requirements)
- 20 CSR 2220-5.025 (Termination of Business as a Drug Distributor)
- 20 CSR 2220-5.030 (Definitions and Standards for Drug Wholesale and Pharmacy Distributors)
- 20 CSR 2220-5.040 (Drug Distributor Inspection Exemptions)
- 20 CSR 2220-5.050 (Out-of-State Distributor License/Registration Requirements)
- 20 CSR 2220-5.060 (Controlled Substance Reporting)
- 20 CSR 2220-5.070 (Standards of Operation for Medical Gas Distributors)
- 20 CSR 2220-6.100 (Pharmacy Standards for Dispensing Blood-Clotting Products)
- 20 CSR 2220-7.010 (General Licensing Rules)
- 20 CSR 2220-7.025 (Intern Pharmacist Licensure)
- 20 CSR 2220-7.027 (Approved Missouri Schools/Colleges of Pharmacy)
- 20 CSR 2220-7.030 (Pharmacist Licensure by Examination)
- 20 CSR 2220-7.040 (Foreign Graduates)
- 20 CSR 2220-7.050 (License Transfer/Reciprocity)
- 20 CSR 2220-7.060 (Score Transfer)
- 20 CSR 2220-7.070 (Temporary RPh License- Post Graduate Training)
- 20 CSR 2220-7.080 (Pharmacist License Renewal & Continuing Education)
- 20 CSR 2220-7.090 (Fingerprint Requirements)

Pursuant to Executive Order 17-03, the Board hosted 4 public hearings in FY 18 to accept comments/suggestions from the public on Board rules. Notice of the public hearings was posted on the Board's website; The public was invited to submit oral, written or electronic comments in advance or in-person.



